

PGPUB-DOCUMENT-NUMBER: 20040060569
PGPUB-FILING-TYPE: new
DOCUMENT-IDENTIFIER: US 20040060569 A1

TITLE: Surface topography method for determining effect of a botulinum toxin upon a muscle

PUBLICATION-DATE: April 1, 2004

INVENTOR-INFORMATION:

| NAME | CITY | STATE | COUNTRY |
|----------------|---------------|-------|---------|
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ASSIGNEE-INFORMATION:

| NAME | CITY | STATE | COUNTRY | TYPE CODE |
|-----------------------|------|-------|---------|-----------|
| <u>Allergan, Inc.</u> | | | | 02 |

APPL-NO: 10/663041 [PALM]
DATE FILED: September 15, 2003

RELATED-US-APPL-DATA:

Application 10/663041 is a continuation-in-part-of US application 10/099602, filed March 14, 2002, US Patent No. 6688311

INT-CL-PUBLISHED: [07] A61B 19/00

INT-CL-CURRENT:

| TYPE | IPC | DATE |
|------|--------------------|----------|
| CIPP | <u>A61 K 49/00</u> | 20060101 |

US-CL-PUBLISHED: 128/898

US-CL-CURRENT: 128/898

REPRESENTATIVE-FIGURES: 1

ABSTRACT:

A skin topographical method for quantifying pharmacodynamic parameters of a paralytic effect of a Clostridial toxin, such as a botulinum toxin upon a muscle, such as a frontalis muscle.

CROSS REFERENCE

[0001] This application is a continuation in part of application Ser. No. 10/099,602, filed Mar. 14, 2002, the entire content of which prior application is incorporated herein by reference.

DOCUMENT-IDENTIFIER: US 20040060569 A1

TITLE: Surface topography method for determining effect of a botulinum toxin upon a muscle

Abstract Paragraph:

A skin topographical method for quantifying pharmacodynamic parameters of a paralytic effect of a Clostridial toxin, such as a botulinum toxin upon a muscle, such as a frontalis muscle.

Assignee Organization Name:

Allergan, Inc.

CLAIMS:

1. A method for determining an effect of a botulinum toxin upon a muscle, the method comprising the steps of: (a) making a first impression of a skin surface in proximity to a muscle into or in the vicinity of which a botulinum toxin will be administered, the impression being made while the muscle is at a first maximum voluntary contraction; (b) administering the botulinum toxin to the muscle; (c) making a second impression of the skin surface in proximity to the muscle, the impression being made while the muscle is at a second maximum voluntary contraction; (d) examining an impression by illuminating an impression with a single light source, and; (e) determining an effect of a botulinum toxin upon the muscle.
2. The method of claim 1, further comprising after the examining step and before the determining step, the step of obtaining from an impression a mean depth of a skin wrinkle.
3. The method of claim 1, further comprising after the examining step and before the determining step, the step of obtaining from an impression a mean length of a skin wrinkle.
4. The method of claim 1, further comprising after the examining step and before the determining step, the step of obtaining from an impression a total length of a skin wrinkle.
5. The method of claim 1, further comprising after the examining step and before the determining step, the step of obtaining from an impression a total number of skin wrinkles.
6. The method of claim 1, further comprising after the examining step and before the determining step, the step of obtaining from an impression a surface area of a skin wrinkle.
7. The method of claim 1, further comprising after the examining step and before the determining step, the step of obtaining from an impression a form factor skin characteristic.
8. the method of claim 1, wherein the determining step determines a paralytic effect of the botulinum toxin upon the muscle
- 9 A method for determining a paralytic effect of a botulinum toxin upon a muscle, the method comprising the steps of: (a) making a first impression of a skin surface in proximity to a muscle into or in the vicinity of which a botulinum toxin will be administered, the first impression being made while the muscle is at a first maximum voluntary contraction; (b) administering the botulinum toxin to the muscle; (c) making a second impression of the skin surface in proximity to the muscle, the second impression being made while the muscle is at a second maximum voluntary contraction; (d) examining an impression by illuminating an impression with a single light source; (e) obtaining from an impression

mean depth, mean length, total length, number of wrinkles, surface area and form factor skin surface characteristics, and; (f) determining a paralytic effect of a botulinum toxin upon the muscle.

10. The method of claim 9, wherein the botulinum toxin is selected from the group consisting of botulinum toxin types A, B, C, D, E, F and G.

11. The method of claim 9, wherein the botulinum toxin is a botulinum toxin type A.

12. A method for determining an effect of a botulinum toxin upon a muscle, the method comprising the steps of: (a) making a first impression of a skin surface in proximity to a muscle into or in the vicinity of which a botulinum toxin will be administered, the impression being made while the muscle is at a first maximum voluntary contraction; (b) administering a botulinum toxin to the muscle; (c) making a second impression of the skin surface in proximity to the muscle, the impression being made while the muscle is at a second maximum voluntary contraction; (d) examining an impression; (e) obtaining from an impression mean depth of a skin wrinkle, and; (f) determining an effect of a botulinum toxin upon the muscle.

13. The method of claim 12, wherein the obtaining step further comprises obtaining from an impression a mean length of a skin wrinkle.

14. The method of claim 12, wherein the obtaining step further comprises obtaining from an impression a total length of a skin wrinkle.

15. The method of claim 12, wherein the obtaining step further comprises obtaining from an impression a total number of skin wrinkles.

16. The method of claim 12, wherein the obtaining step further comprises obtaining from an impression a surface area of a skin wrinkle.

17. The method of claim 12, wherein the obtaining step further comprises obtaining from an impression a form factor skin surface characteristic.

18. The method of claim 12, wherein the determining step determines a paralytic effect of the botulinum toxin upon the muscle

19. The method of claim 12, wherein the botulinum toxin is selected from the group consisting of botulinum toxin types A, B, C, D, E, F and G.

20. The method of claim 12, wherein the botulinum toxin is a botulinum toxin type A.

21. A method for determining an effect of a botulinum toxin upon a muscle, the method comprising the steps of: (a) making a first impression of a skin surface in proximity to a muscle into or in the vicinity of which a botulinum toxin will be administered, the impression being made while the muscle is at a first maximum voluntary contraction; (b) administering the botulinum toxin to the muscle; (c) making a second impression of the skin surface in proximity to the muscle, the impression being made while the muscle is at a second maximum voluntary contraction; (d) examining an impression; (e) obtaining from an impression mean skin wrinkle depth, mean skin wrinkle length, total skin wrinkle length, total number of skin wrinkles, surface area of a skin wrinkle and form factor skin surface characteristics, and; (f) determining a paralytic effect of a botulinum toxin upon the muscle.

DOCUMENT-IDENTIFIER: US 20050261632 A1

TITLE: High-Aspect-Ratio Microdevices and Methods for Transdermal Delivery and Sampling of Active Substances

CLAIMS:

10. A method of using the devices as defined in claim 1 for treating, preventing, or ameliorating a body condition, comprising pushing a plurality of microneedles through the outer layer of skin or scratching a plurality of microblades or microknives on a preselected site of the skin, and followed by applying a skin patch containing active agents over the preselected skin site.

11. A method of using the devices as defined in claim 4 for treating, preventing, or ameliorating a body condition, comprising pushing a plurality of microdevices through the outer layer of skin or scratching a plurality of microdevices at a preselected skin site.

13. The method of claims 10 and 11, wherein the active agent is a cosmetic substance selected from the group consisting of botulinum toxin type A, hyaluronic acid and its derivatives, acetyl hexapeptide-3, vitamin A, vitamin C, vitamin E, alpha-hydroxyacids, collagen and hormones.

17. The method of claim 10, wherein the microdevice performs topical delivery of active agent defined in the claims 12, 13, 14 and 15.

19. The method of claim 18, wherein the medical condition is one or plurality of AIDS, breast cancer, melanoma, liver cancer, lung cancer, blood cancer, pituitary tumors, other cancers, flu, infection, blood disease, cardiac disease, back pain, neck pain, body pain, general pain, arthritis, osteoporosis, headache, depression, smoke, alcoholic, overweight and obesity, menopause, facial hair growth, balding, polycystic ovary syndrome, need of inoculation, need of anesthetics and in particular dermal disease.

20. The method of claim 18, wherein the cosmetic condition is one or plurality of skin aging, skin wrinkle, dark spot, skin discoloration, moisturizing, skin lightening, skin whitening, skin firming, skin lifting, acne, wart, infection, irritation, dry skin and oily skin.

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File: PGPB

Jul 27, 2006

DOCUMENT-IDENTIFIER: US 20060165657 A1

TITLE: Method for delivery of cosmetic by topical application

CLAIMS:

5. The composition of claim 1, wherein the heterologous nucleic acid encodes botulinum toxin.

6. The composition of claim 5, wherein the botulinum toxin is selected from the group consisting of botulinum toxin A, B, C.sub.1, D, E, F and G.

8. A method of delivering a heterologous nucleic acid to a mammalian target cell, comprising contacting the skin of the mammal with the composition of claim 1, under conditions whereby the baculovirus vector is introduced into the target cell.

15. The method according to claim 12, wherein the baculovirus is administered topically.

17. A method of reducing skin wrinkles in a mammal, comprising contacting the composition of claim 5 with the skin of the mammal under conditions whereby the baculovirus vector is delivered to a target cell, heterologous nucleic acid is expressed to produce botulinum toxin and the botulinum toxin is delivered to a nerve cell associated with a muscle involved in a wrinkle, thereby reducing skin wrinkles in the mammal.

18. A method of tanning the skin of a mammal, comprising contacting the composition of claim 1 with the skin of the mammal, wherein the heterologous nucleic acid encodes a melanocyte modulatory protein and/or keratinocyte modulatory protein under conditions whereby the baculovirus vector is delivered to a target cell, the heterologous nucleic acid is expressed to produce the melanocyte modulatory protein and/or keratinocyte modulatory protein and the melanocyte modulatory protein and/or keratinocyte modulatory protein is delivered to melanocytes and/or keratinocytes, thereby tanning the skin of the mammal.

19. A method of reducing the incidence of acne in the skin of a mammal, comprising contacting the composition of claim 1 with the skin of the mammal, wherein the heterologous nucleic acid encodes androgen receptor and/or 5.alpha. reductase under conditions whereby the baculovirus vector is delivered to a target cell, the nucleic acid is expressed to produce the androgen receptor and/or 5.alpha. reductase and the androgen receptor and/or 5.alpha. reductase is delivered to sebaceous gland cells, thereby reducing the incidence of acne in the skin of a mammal.

20. A method of diminishing the appearance of a scar in the skin of a mammal, comprising contacting the composition of claim 1 with the skin of the mammal, wherein the heterologous nucleic acid encodes a [protein] under conditions whereby the baculovirus vector is delivered to a target cell, the heterologous nucleic acid is expressed to produce the protein and the protein is delivered to an effector cell, thereby diminishing the appearance of the scar.

21. A method of reducing a fat deposit in the skin of a mammal comprising contacting the composition of claim 1 with the skin of the mammal, wherein the heterologous nucleic acid encodes a protein selected from the group consisting of uncoupling protein-1, uncoupling protein-2, uncoupling protein-3, and .beta.-adrenergic receptor 3, under conditions whereby the baculovirus vector is delivered to a target cell, the heterologous nucleic acid is expressed to produce the gene product of the heterologous nucleic acid and the gene product is delivered to an adipocyte, thereby reducing a fat deposit in the skin of the mammal.

22. A method of reducing perspiration in the skin of a mammal, comprising contacting the composition of claim 1 with the skin of the mammal, wherein the heterologous nucleic acid encodes sodium bicarbonate under conditions whereby the baculovirus vector is delivered to a target cell, the heterologous nucleic acid is expressed to produce sodium bicarbonate and sodium bicarbonate is delivered to neuronal cells, thereby reducing perspiration in the skin of a mammal.

23. A method of delivering vitamin E to a cell in the skin of a mammal comprising contacting the composition of claim 1 with the skin of the mammal, wherein the heterologous nucleic acid encodes vitamin E under conditions whereby the baculovirus vector is delivered to a target cell, the heterologous nucleic acid is expressed to produce vitamin E and vitamin E is delivered to an effector cell that metabolizes vitamin E, thereby delivering vitamin E to the skin of the mammal.

24. A method of reducing hair growth in the skin of a mammal comprising contacting the composition of claim 1 with the skin of the mammal, wherein the heterologous nucleic acid encodes a protein under conditions whereby the baculovirus vector is delivered to a target cell, the heterologous nucleic acid is expressed to produce the gene product of the heterologous nucleic acid and the gene product is delivered to an epithelial cell, thereby reducing the appearance of hair growth in the skin of the mammal.

25. A method of changing hair color in a mammal comprising contacting the composition of claim 1 with the skin of the mammal, wherein the heterologous nucleic acid encodes a protein under conditions whereby the baculovirus vector is delivered to a target cell, the heterologous nucleic acid is expressed to produce the gene product of the heterologous nucleic acid and the gene product is delivered to an epithelial cell, thereby increasing the hair color and/or growth of hair in the skin of the mammal.

26. A method of reducing signs of aging in the skin of a mammal comprising contacting the composition of claim 1 with the skin of the mammal, wherein the heterologous nucleic acid encodes a modulatory, protein under conditions whereby the baculovirus vector is delivered to a target cell, the heterologous nucleic acid is expressed to produce the gene product of the heterologous nucleic acid and the gene product is delivered to a keratinocyte, thereby reducing signs of aging in the skin of the mammal.

27. A method of inducing apoptosis in a cell in the skin of a mammal, comprising contacting the composition of claim 1 with the skin of the mammal, wherein the heterologous nucleic acid encodes a protein under conditions whereby the baculovirus vector is delivered to a target cell, the heterologous nucleic acid is expressed to produce the gene product of the heterologous nucleic acid and the gene product is delivered to an effector cell that cause apoptosis, thereby inducing apoptosis in a cell in the skin of a mammal.

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[0041] Certain compositions of the invention are useful to reduce fine lines and wrinkles, increase the moisture level of the skin, increase skin elasticity and resilience, increase the firmness of the skin, improve skin tone, texture and overall radiance, diminish bags under the eyes, rejuvenate the skin, prevent damage from chemical stress, protect the skin from UV rays and free-radical damage, promote wound healing and remove irregular pigmentation. Specific compositions of the invention may be useful to treat pain.

BRIEF DESCRIPTION OF THE DRAWINGS

[Generate Collection](#)[Print](#)*Search notes***Search Results - Record(s) 1 through 33 of 33 returned.**

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| (5 AND 3).PGPB,USPT,USOC,EPAB,JPAB,DWPI,TDBD. | 33 |
| (L5 AND L3).PGPB,USPT,USOC,EPAB,JPAB,DWPI,TDBD. | 33 |

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vicinity



vi·cin·i·ty [və sínətee] (*plural* vi·cin·i·ties)

noun

Definition:

1. surrounding region: a neighborhood, or the area surrounding a particular place

- *The fire threatened to spread, and all the houses in the vicinity had to be evacuated.*

2. proximity: the fact of being close either in space or relationship

[Mid-16th century. < Latin *vicinitas* < *vicinus* "neighbor" < *vicus* "village, homestead"]

In the vicinity of

1. close to, neighboring, or surrounding
2. roughly or approximately

in the vicinity of


approximately:

The team is believed to have paid in the vicinity of £3 million for Domingo.

The American Heritage® Dictionary of the English Language: Fourth Edition. 2000.

vicinity

SYLLABICATION: vi·cin·i·ty

PRONUNCIATION:  vĭ-sĭn'ĭ-tē

NOUN: Inflected forms: pl. **vi·cin·i·ties**

1. The state of being near in space or relationship; proximity: *two restaurants in close vicinity*. **2.** A nearby, surrounding, or adjoining region; a neighborhood. **3.** An approximate degree or amount: *houses priced in the vicinity of \$200,000*.

ETYMOLOGY: Latin *vīcīnitās*, from *vīcīnus*, neighboring, from *vīcus*, neighborhood. See **weik-**¹ in Appendix I.

WEST Search History

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| <input type="checkbox"/> | L1 | allergan.asn. | 3078 |
| <input type="checkbox"/> | L2 | L1 and (skin or dermal or topically or topical or intradermal or melann or pigment or dermatofibromas or fibromas or dermoid or freckles or keloids or seborrheic or keratoses or actinic or albinism or melasma or vitiligo or damage).clm. | 195 |
| <input type="checkbox"/> | L3 | L2 and (method or process).clm. | 179 |
| <input type="checkbox"/> | L4 | (method or process).clm. same (skin or dermal or topically or topical or intradermal or melann or pigment or dermatofibromas or fibromas or dermoid or freckles or keloids or seborrheic or keratoses or actinic or albinism or melasma or vitiligo or damage).clm. | 63661 |
| <input type="checkbox"/> | L5 | L4 and (botulin or botulinum or botox or bont or bonta or bnt or bonta or bnta or bontoxylysin or bontox or bot-tox or dysport or myobloc or neurotoxin).ti,ab,clm. | 145 |
| <input type="checkbox"/> | L6 | L5 and l3 | 33 |
| <input type="checkbox"/> | L7 | l5 not l6 | 112 |

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